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December 10, 2019

VIA ECF
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Plaintiffs submit this Letter Brief in response to Defendants' brief concerning custodians, search terms, ESI related issues, and document request to Manufacturer Defendants.

I. Preliminary Statement

Over the last three months, Plaintiffs have conducted hundreds of hours of meet-and-confers with Defendants. Plaintiffs have written countless letters identifying categories of documents which they believed to be critically important to the case. Plaintiffs have provided annotated custodian lists, with dozens of core discovery references and justifications for those custodians, and did so for multiple Defendants. Plaintiffs have provided search terms, and

explanations of those search terms (terms Plaintiffs identified, in part, after hundreds of hours reviewing core discovery documents). Plaintiffs have narrowed their requests, both in the context of meet-and-confers, and in the context of amended discovery pleading documents. And yet, Defendants describe Plaintiffs' conduct as "an abuse of the discovery process" in their most recent letter to the Court. *See* Goldberg Ltr. at 1.

The truth is, the discovery process has become stalled because Defendants refuse to produce internal documentation, either as exemplar documents for search terms, or documents provided to the FDA as part of investigations. Defendants have further resisted efforts on meet-and-confers to provide additional information orally, or in writing. Instead, Defendants rest on their core discovery production,[1] using it both as a shield (to deny Plaintiffs any explanation during meet-and-confers) and a sword (pointing to the absence of names or information as a rationale for precluding discovery). Unquestionably core discovery has been extremely beneficial and has enabled Plaintiffs to more precisely ask for the documents they require for certain specific areas (such as regulatory documents, and manufacturing documents). This is evidenced by Plaintiffs' detailed seven-page letter describing the manufacturing documents they are seeking. *See* Pls. Ltr. at Ex. 1.

However, core discovery has no bearing on documents related to many highly relevant subjects, including but not limited to: warranties, API sales, API marketing, contracts with vendors, contracts with outside laboratories, procurement, pricing, reimbursement, and the like.

[1] It should be noted that the core discovery production is necessarily a very sanitized set of documentation. Each correspondence sent to the FDA has been through multiple layers of lawyer-driven vetting and review (and in some cases, review by *lawyers who are also Counsel in this action*).

It is these areas where Plaintiffs need assistance and cooperation from Defendants (in the form of explanations of department, descriptions of employees' tenures and responsibilities, and affirmative information about sales data and how it is kept) in order to narrow requests, create custodian lists, and develop search terms. Defendants have largely provided no such assistance. Plaintiffs are hard pressed to narrow requests further without Defendants' participation.

II. Custodians

a. ZHP

ZHP admits to hundreds of potential custodians, stating that it "manufactures valsartan API in four workshops, meaning that anywhere from 80 to 320 employees work on valsartan at the manufacturing level. And that number does not include the managers assigned to those workshops, or the directors supervising the managers, or the quality assurance personnel who are in the room observing each step of the process." And then there are the employees in other departments with other responsibilities regarding valsartan, such as regulatory. *See* Goldberg Ltr. at 11). Moreover, this number does not include employees of Huahai US, Prinston, Solco (collectively with ZHP, the "ZHP Defendants"), Shanghai Syncores, or Prinbury. The ZHP Defendants began this process by proposing a scant eight custodians, which did not include Jun Du or the twenty-seven custodians that they subsequently admit are proper. Given the vast gulf between the number of employees who worked on valsartan the number of custodians proposed by Plaintiffs is modest. In comparison, this Court ordered searches of the files of 230 custodians in *Benicar*, including 115 Daiichi US custodians, 68 Daiichi Japan custodians, and 47 Forest custodians. *See* Exs. 2 & 3.

Even at this late stage, Plaintiffs have continued to pursue information through the meet-and-confer process. On December 2, 2019, ZHP served four organization charts regarding their Xunqiao facility that manufactured finished dose Valsartan, completely in the Chinese language. Six days later, ZHP provided English translations of those charts, identifying two individuals whom ZHP had agreed were proper custodians (Minli Zhang, Xiaoming Liu), four whom Plaintiffs had previously proposed and ZHP had not accepted or disputed (Xiaoling Li, Yuping Chen, Youqing Zheng, Lina Wu), and forty-seven new names. (Ex. 4). Plaintiffs reviewed the translated charts and asked ZHP to discuss them, which occurred on December 10, 2019.

At the December 10, 2019 meet and confer, ZHP's counsel advised that it was not prepared to discuss all of the potential custodians in the organization charts, explaining that they had not investigated everyone on the charts, and in particular whether and to what extent they had involvement with Valsartan. ZHP said that the only people "meaningfully involved in Valsartan" who were named in the charts were the two individuals whom it had previously proffered, despite the fact that they had not investigated all of the custodians.[2] When asked about people who were listed on the charts below the agreed-to custodians, ZHP admitted that they worked on Deviation Reports and Out-of-Specification Investigation Reports related to Valsartan, yet they would not agree to include them. Obviously, these are proper custodians. Upon further inquiry into the individuals below Xiaoling Li and Chen Yuping as well as those in

[2] ZHP seemed to base this position on the idea that Xiaoling Li and Chen Yuping "routinely" worked on many different drugs, not just Valsartan. However, a person does not have to work solely on Valsartan in order to be a custodian in this case. Rather, the standard is whether they are likely to have relevant and probative documents, which certainly include custodians who prepared Valsartan Deviation Investigation and Out-of-Specification Reports as well as all the documents created during those investigations at all levels.

other areas of the organization chart, ZHP's counsel informed Plaintiffs that they had not asked their client about these specific individuals. Plaintiffs have updated their custodian list and included same as Exhibit 5 to this brief.

Instead of providing the information necessary for a meaningful meet-and-confer process, the ZHP Defendants continue to advocate for an arbitrary limit on custodians, without regard to the merits. The ZHP Defendants admit that they have "more detailed factual" information about each of Plaintiffs' proposed custodians, but concede that they have not provided it to date. The ZHP Defendants cite three unpublished cases – including *Enslin v. Coca-Cola Co.*, No. 2:14-cv-06476, 2016 WL 7042206 (E.D. Pa. June 8, 2016), in defense of their approach, but the cases cut directly against their position. (Defs.' Br. 10). This is made clear by a recent published decision that discusses *Enslin*:

> Defendants claim that the additional custodians would be cumulative and duplicative and that the cross-section represented by the original eighteen custodians was sufficient, but this assertion is speculative. **Indeed, although Defendants contend that the original custodians were a "representative population,"** Defs.' Reply at 3, **this claim is unsupported by either statistical evidence or logical analysis. Defendants also cite to *Enslin*, but the movants in that case had shown that each document captured by an additional custodian was already captured by a prior custodian searched.** *See Enslin*, 2016 WL 7042206, at *3. **Here, Defendants have not shown such a degree of overlap.**

Garcia Ramirez v. U.S. Immigration and Customs Enforcement, 331 F.R.D. 194, 197 (D.D.C. 2019). This analysis is equally applicable here, as the ZHP Defendants have also failed to make such a showing (and cannot as they have refused to search or test any potential custodial files

until the custodians and search terms are set). In *Ramirez*, the court entered an order that the proposed custodians were proper, as should occur on the record here. *Id.* at 199.

The ZHP Defendants apparently hope that the Court will perform no substantive analysis and arbitrarily limit the Plaintiffs to fifty custodians. In pursuit of this strategy, ZHP points to the number of custodians agreed to/at issue with regard to other Defendants. Importantly, the number of other Defendants' custodians is a red herring. Rather, the Court should evaluate each Defendant's custodians in the context of that specific defendant's role(s) in the case, its corporate organization, and business practices.

Based on the record before the Court, this Court should enter an order adopting Plaintiffs' proposed list of custodians.

b. Teva

On December 4, 2019 (the night before the parties' December 5 opening letter briefs were due), Teva agreed to several additional custodians proposed by Plaintiffs. Today, during a subsequent meet-and-confer, Teva agreed to additional custodians. The total agreed-upon custodians currently stands at 34. While Teva complains Plaintiffs proposed their revised list of custodians on November 25, they neglect to mention they refused to produce *any* organizational charts until November 15. Once Plaintiffs received those (incomplete) charts, they diligently identified additional custodians and, by way of compromise, dropped their requests for several other custodians previously identified through Plaintiffs' exhaustive review of core discovery.

Teva still owes Plaintiffs information on several custodians proposed by Plaintiffs, for whom Teva had no additional information on December 4. Plaintiffs hope to be able to reach full agreement with Teva by December 11 or, at the very latest, December 18.

c. Torrent

As of now the Parties have agreement on 18 custodians. However, Torrent still has additional information it needs to receive from its client in India regarding departments and persons identified from Torrent's organizational chart production. There are approximately 13 such individuals for which Plaintiffs have requested additional information. In the spirit of cooperation, having agreed on many of the material custodians, the Parties have agreed to a cap on custodians not to exceed 25 individuals. The Parties intend to talk by the end of this week, or during the weekend, to finalize the total list.

d. Aurobindo

At issue with Defendant Aurobindo are an outstanding 4 custodians. In the interest if compromise, and in light of the fact that Counsel still needs to get more information from Aurobindo, the Parties have agreed to a cap of 15 custodians, which would include some subsection of these four outstanding custodians which still remain.

III. Search Terms

Based upon the Court's suggestion and guidance, the parties have met and conferred further and have resolved three out of the four categories of documents in dispute, as detailed below. The only remaining category in dispute relates to the 17 terms objected to by Defendants on the Plaintiffs' proposed cGMP primary terms list.

A. Resolved Issues

Plaintiffs believe that their primary search terms and modifiers categories and suggested search combinations are proper. Defendants believe that many of these terms and modifiers, as proposed, will require substantial unnecessary efforts and cost. The Parties continue to be

willing to refine and narrow these search terms in order to reduce unnecessary efforts and cost while also minimizing the risk that relevant documents will be excluded and therefore not be reviewed for responsiveness to Plaintiffs' document requests. To that end, the Parties have devised and agreed upon the detailed method described below for further evaluating disputed search terms while simultaneously reviewing and producing non-custodial documents and documents resulting from undisputed search terms. The Parties respectfully submit that this procedure will allow for the most expeditious rolling production of documents by Defendants while giving the Parties the ability to further refine the search terms as necessary based upon actually collected documents and data.

1. **Standalone Terms**

   a) The following terms shall remain on the standalone terms list but can be tested and refined further if a need is shown after documents are collected and preliminarily reviewed:

      i. *diethylamine or "*diethyl amine"
      ii. *dimethylamine or "*dimethyl amine"
      iii. *dimethylformamide or DMF
      iv. *dimethylmethanamide
      v. *ghost*
      vi. *NDEA*
      vii. *NDMA*
      viii. *nitra*
      ix. *nitrite*
      x. *nitrosa*
      xi. *nitroso*
      xii. *trosomine*
      xiii. C2H6N2O or "(CH3)2NN=O" or "CH32NN=O" or "(CH3)2NC(O)H" or CH32NCOH or C3H7NO or "(CH3CH2)2NH" or CH3CH22NH or C4H11N or "(CH3)2NH" or CH32NH or C2H7N or "(C2H5)2NNO" or C2H52NNO or C4H10N2O
      xiv. tetrazol*

xv. gene* /3 mutat*
xvi. genotoxic*
xvii. carcin* (but may modify if needed)
xviii. deviat* /5 cancer* or deviat* /5 toxic or deviat* /5 hazard* or deviat* /5 fatal (but may modify if needed)
xix. FDA /10 warning (but may modify if needed)
xx. solvent /5 cancer* or solvent /5 toxic or solvent /5 hazard* or solvent /5 fatal (but may modify if needed)
xxi. solvent* /5 contamin* (but may modify if needed)
xxii. Valisure* (but may modify if Valisure comes up for a reason other than its role in relation to detecting nitrosamines).

b) The following terms (1) when used against data of custodians working only at a particular facility would be run as standalone terms; and (2) when used against data of custodians in management over more than one facility would be run with <term> AND (<Drug Name> OR <Solvents> OR <Facility Name>), but can be tested and refined further to be <term> AND <facility name> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>)) if needed:

i. EIR or "establishment inspection report"
ii. OAI or "official action indicated"
iii. "voluntary action indicated"
iv. (Form483) or (Form /3 483) or (483 /3 letter) or (483 /3 warn*) or (704 pre/3 b)

c) The following terms shall be moved to the Manufacturing primary terms list:

i. diastereo*
ii. moiety or moieties
iii. *formaldehyde*

d) The term "test* /5 canc*" can be run as follows: <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>))

e) The inclusion or modification of NMBA will be decided after the JPML's decision on expansion of the MDL.

2. **Manufacturing, Medical Conditions, Economic Terms, Entities**

   a) The search string for these primary terms categories will be changed to: <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>)) where <other drug names> will be an agreed to list of the names of each other non-valsartan (or other sartan depending on the JPML's ruling) drug manufactured by the defendant running the modifiers;

   b) Plaintiffs will identify a subset of these terms that they believe need to be run with <Term> AND (<Drug Name> OR <Solvents>) instead (i.e. without excluding other drug names), which will be subject to testing and sampling as to the differential results;

   c) Any terms still in dispute after such testing, sampling, and meet and confers will be promptly brought to the Court for resolution.

3. **QA-Testing, cGMP (two undisputed terms), and Regulatory**

   a) The search string for these will be changed to: <Term> AND (<Drug Name> OR (<Solvents> AND NOT <other drug names>)) OR [other categories of modifiers]);

   b) The Parties will negotiate any further modifications in either direction (e.g. narrowing or broadening), if needed, once documents have been collected and initially reviewed.

   c) Any terms still in dispute after such testing, sampling, and meet and confers will be promptly brought to the Court for resolution.

4. **31 Terms Completely Objected to by Defendants**

   a) Defendants will run hit counts using the search string agreed upon for each particular term for those terms Defendants objected to as "overly generic terms" or "overly generic terms in light of defendants' business";

   b) The hit counts will be reviewed, documents sampled if necessary, and the Parties will meet and confer on how to narrow the terms if needed;

   c) If the Parties cannot agree, they will promptly bring the issue to the Court for resolution.

Thus, at this time, the Parties do not require the Court's intervention with regard to the above categories of search terms. As detailed above, if the Parties cannot agree on any remaining disputes once documents have been collected and a preliminary review has been conducted, the Parties will promptly, and to the extent practicable, jointly bring the issue before the Court for resolution.

B. Remaining Dispute as to cGMP Terms

Plaintiffs have proposed a sub-section of search terms[3] related to the potential destruction of Defendants' potential data and/or lab test results/documents. Defendants purposefully misconstrue the purpose of these terms in their letter by labeling them as legal "spoliation" related search terms. Defendants do so in order to take the position that the terms are inappropriate because there are not sufficient grounds to argue for spoliation-related discovery. However, Plaintiffs do not seek inclusion of these terms to argue for a spoliation inference.

[3] It is important to note that Plaintiffs only seek to run these terms against the custodians at issue in this case.

Plaintiffs seek inclusion of these terms because destroying data, and shredding original lab documents violate cGMPs. Indeed, as an example, 21 CFR § 211.180 provides that documents must be retained for at least 1 year after the expiration of a batch, must be readily available for authorized inspection, and must be retained as either original records or true copies. Documents which are required to be maintained under § 211 include (but are not limited to), standard operating procedures, specification, standards, sampling plans, test procedures, and other laboratory controls, and documentation of all complaints, deviation reports, OOS or OOT findings. Plaintiffs inclusion of these terms are an attempt to identify whether Defendants were complying with these obligations.

The specific terms in dispute are:

1. (bottle pre/2 lies) or Eban
2. bury or burie* or conceal*
3. "cover up*" or coverup* or "cover-up*"
4. crash* or disaster*
5. delet* or destroy* or remov* or trash* or shred*
6. hide* or suppress*
7. whistleblow*

Defendants themselves have made this discovery germane by repeatedly arguing that there were no tests that could have captured nistrosamine impurities prior to 2018.[4] Plaintiffs are entitled to rebut this argument with evidence (to the extent it exits) that Defendants were, for

[4] *See* June 26, 2019, CMC Tr. at 28:25-29:5 (Mr. Trischler: "The FDA actually developed what it called an innovative test to check for NDMA and NDEA, conducted some testing, notified manufacturers, asked manufacturers to conduct testing.").

example, actively destroying or shredding original lab records of chromatography data.[5] Furthermore, Plaintiffs did not manufacture these terms from thin air, they were derived after reviewing inspection reports from the FDA, which detailed cGMP violations related to document and data destruction. *See* Ex. 8, Hetero 483 ("…your QA technicians and other individuals were recorded *destroying* and altering records pertaining to commercial batch manufacturing…" (emphasis added), *id.* ("we observed extensive *shredding* of….controlled documents") (emphasis added), *id.* ("..in the *trash bin*…we observed…original test results"); *see, also*, ECF 296, Ex. 2 ("…we found numerous [QC and QA] documents in the *shredding bins*…") (emphasis added).

Given the nature (and small quantity) of the terms, not to mention the fact that the terms would be run against modifiers and only on the custodians at issue in this case, there is little to no burden to Defendants from searching for these terms. These are not common terms that should appear in the regular course of Defendants' business, particularly in conjunction with the modifiers proposed. If Defendants did not engage in any of these practices that run contrary to cGMP, there should be few to no hits against the requested search terms, and thus few to no documents for Defendants to review. If, however, there are numerous hits against one or more of these terms, given the custodians and modifiers being used, those documents would, in all likelihood, be relevant to the issues in the case. To the extent one or more of these terms and modifier combinations produces a large number of irrelevant hits, just as with the other terms above, Defendants can bring the issue to Plaintiffs and the Parties can meet and confer about

[5] Defendant Mylan, for example, had data integrity with its chromatography testing – a test for which NDMA first presented as an unknown peak. *See* ECF 296, Ex. 3, (2016 Mylan Nashik EIR) at 7 (errors with Empower included, "connection to chromatography system lost"). The FDA inspector noted "150 messages indicating "possible data corruption or modification of file" affecting 12 sequences, and that "data was lost, as it was not captured in the back-up system.").

appropriate narrowing if needed. At this point, however, Defendants have run no hit counts and done no sampling to show that searching for these terms is unduly burdensome or is disproportional. Defendants should not be permitted to ignore highly relevant discovery regarding flagrant non-compliance with cGMPs and evidence of data destruction under the guise of straw-man objections.

C. Translation of the Search Terms

It appears that the vast majority of ZHP's documents are in Chinese. All other Defendants have represented that their documents are in English. Now that the search terms will be finalized upon the Court's ruling on the cGMP issue, Plaintiffs propose that ZHP be given until January 3, 2019 to provide Plaintiffs with their suggested translations. Plaintiffs will have until January 13, 2020 to provide any suggested changes, the Parties will meet and confer, and any issues regarding translated search terms can be decided by the Court at the January 28, 2020 conference.

D. Document Production Timing

While the Parties have agreed that Defendants will begin to produce non-custodial documents first while they collect, search, and review and produce custodial documents on a rolling basis, Plaintiffs are very concerned at the complete lack of production to date. Defendants have known about Plaintiffs' request for them to produce the documents provided to the FDA during its inspections, and those listed as exhibits from the FDA's inspection reports, for months now. The Court has ordered them to produce them expeditiously. Yet, Defendants have yet to produce any of these documents to date. Furthermore, the API Manufacturer Defendants *still* have not produced inspection related documents for their finished-dose

manufacturing facilities. These documents (especially Establishment Inspection Reports) would have been extremely helpful in developing a list of relevant custodians with responsibility for quality assurance functioning at the finished dose facilities. If Defendants are taking this long before producing what should be readily identifiable and producible documents, Plaintiffs are concerned that without this Court setting deadlines, production of the remaining non-custodial documents and custodial documents will not be started, much less completed, in a timely manner.

IV. Plaintiffs' Document Requests

Defendants' December 5 letter brief identifies only two narrow sets of requests in dispute: (i) unapproved, tentatively approved, or withdrawn ANDAs and DMF files, and (ii) sales/pricing data. Plaintiffs' opening letter brief thoroughly addresses both of these subjects (*see* Pls.' Ltr. at 12-15, 34-35). Plaintiffs incorporate their prior arguments herein, and only reply to the specific points raised in Defendants' letter brief.

a. Production of Unapproved, Tentatively Approved or Withdrawn ANDAs and DMF Files

Plaintiffs already explained in their opening letter brief why these particular ANDA and DMF files are highly relevant and discoverable, *viz.*, Defendants' efforts to obtain FDA regulatory approval to manufacture valsartan in one way (that would not result in nitrosamine contamination) is probative of their decisions ultimately to use a *different* manufacturing process that *did* result in nitrosamine contamination. Similarly, differences between the types or sensitivities of the testing Defendants proposed to use, versus what they did use, bears on the sufficiency of their actual testing for nitrosamine contamination.

To the best of Plaintiffs' knowledge, there are only *three* regulatory files at issue here: These include ANDA 204743 (application submitted by Mylan for an amlodipine valsartan HCTZ drug, which was initially submitted in 2012 but remains pending and *still* has not received approval), ANDA 210596 (an application submitted by ZHP for Valsartan Nebivolol which has not been approved), and a Drug Master File submitted by Teva for the manufacture of Valsartan, which Plaintiffs only very recently identified in the context of other research of publicly available sources.[6]

i. ZHP and Mylan Unapproved ANDA Applications

Plaintiffs seek production of a mere two ANDA applications – one for Mylan's amlodipine valsartan HCTZ product, and ZHP's valsartan nebivolol product. Plaintiffs should be afforded this discovery because it is a discrete production of documents, the contents of which is required by law to be kept and maintained and would be little burden to Defendant Mylan and ZHP to produce. Plaintiffs are unable to obtain this information from any other source. To the extent the Defendants have any proprietary business information concerns.[7] the protective order explicitly provided with a "restricted confidential" designation to alleviate such issues.

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[6] This list represents the totality of other ANDA applications or DMF files located by Plaintiffs. Plaintiffs are unaware of other unapproved ANDA applications for any valsartan containing drug (or, for that matter, any DMF for the valsartan molecule), but the Court should compel Defendants to disclose whether they have any unapproved ANDA applications for a valsartan containing drug. Plaintiffs note that Teva appears to have an ANDA application for generic Entresto, which is a valsartan sacubitril combination product, and a DMF on file for that same valsartan sacubitril molecule. However, in the interest of cooperation, Plaintiffs do not seek production of these two files at this time, as it is Plaintiffs' understanding that the valsartan saccubritil molecule is different from the pure valsartan molecule at issue in this litigation.

[7] Defendants' proprietary business concerns are without merit. Mylan's ANDA application is for a generic product which has been on the market since 2012. This is not a new, groundbreaking drug molecule. The brand reference listed drug for ZHP's valsartan nebivolol product has

With respect to Mylan's unapproved ANDA (No. 204743), the need for this ANDA (and all correspondence associated with it) cannot be disputed. First, Plaintiffs are entitled to discover why this particular application, submitted in 2012, has not yet received approval, 7 years later, despite all other Mylan VCD products coming to market. Defendants appear to argue that Plaintiffs should only be entitled to communications with the FDA about this unapproved ANDA to the extent that it discusses nitrosamine contamination, but that is unnecessarily restrictive. If Mylan's ANDA application for this product has not been approved because of cGMP compliance issues – and there is evidence to suggest that this was the case –Plaintiffs are entitled to discover this correspondence and understand precisely which cGMP issues the FDA sought to remedy prior to approval, and why these issues precluded approval.

With respect to ZHP's tentatively approved ANDA application (No. 210596) for generic Byvalson (which is a combination of valsartan and nebivolol), Plaintiffs have found no reference to this ANDA application in Prinston's core discovery production. This is curious because, the FDA would be communicating with ZHP about this ANDA to the extent ZHP was relying on their Valsartan DMF at issue in this case for their drug manufacturing (as was the case with Mylan's unapproved ANDA). But there is no such discussion in the communications. Plaintiffs are entitled to know if there was a third process ZHP was using for this Valsartan product, or if ZHP actually intended to purchase API elsewhere from another source for this product. Furthermore, this ANDA application was the subject of a protracted patent litigation before Judge Martinotti in the District of New Jersey. *See* 3:17-cv-07191-BRM-TJB (D.N.J.)

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actually been withdrawn, so no generic could even sell or market such a drug. Furthermore, Plaintiffs are amenable to redactions removing all references to the manufacturing process associated with nebivolol to alleviate any concerns.

ii. Teva's Drug Master File for Valsartan API

While Defendants previously represented that all DMF files for valsartan processes had been produced in core discovery, Plaintiffs' own research uncovered evidence which suggests otherwise: Plaintiffs have located a 2015 Teva API product catalogue, wherein Teva identified valsartan as one such API they were selling to customers (and indicated there was a DMF on file with the FDA), and identified that Teva utilized *multiple synthesis processes* for the manufacture of that API. *See* Ex. 6. Teva was manufacturing this valsartan API in a factory in India. *See* Ex. 7.

The relevance of this discovery cannot be understated. Indeed, this new information raises many important questions such as: what chemical synthesis process (utilizing which catalysts and solvents) did Teva use for API it sold to customers around the world? Why did Teva purchase API from both Mylan and ZHP to use in their US products if they were actively manufacturing valsartan API for themselves? Did Teva compare the processes when deciding to purchase API from Mylan and ZHP?

While Plaintiffs believe that discovery into all these questions (including more expanded discovery into the Teva API manufacturing process analogous to what Mylan and ZHP are agreeing to provide) would be appropriate, Plaintiffs are attempting to strike a reasonable balance. As such, discovery of the DMF file (which Teva's brochure says is available "upon request" to customers) is more than appropriate, and a very proportionate request in light of the gravity of the public health crisis, and obviously of little burden to Teva.

b. Sales and Pricing Data

Defendants' assertion that Request Nos. 101 an 107 are overly broad and seek "irrelevant" information is simply incorrect. These requests seek transactional data, which, in general terms, will show (i) to whom Defendants sold valsartan API and finished dose, (ii) how much valsartan was sold (i.e., quantity and unique identifiers such as NDC, lot number, batch number, etc.), and (iii) for how much (i.e., gross and net prices). Plaintiffs do not seek sales data for foreign transactions (*see* Defs. Ltr. at 33).

Plaintiffs did not serve a single omnibus simply asking for "all sales data." Instead, Plaintiffs took pains to identify in granular detail the types of data fields or data points routinely maintained by pharmaceutical manufacturers. Plaintiffs might be able to narrow the data fields they need if Defendants provided sample data, or data field dictionaries or information summarizing the types of data each Defendant keeps. But Defendants have refused to provide *any* information whatsoever on what data they keep, and how. Plaintiffs cannot share further detail about what they "really need" (*see* Defs. Ltr. at 312) until Defendants tell Plaintiffs what the universe of extant data is. Then, the parties can meaningfully work through what "really" needs to be produced, and what does not.

c. Requests for Testing

Since the filing of Plaintiffs' initial brief, defendant Mylan sent a letter on December 9, 2019, identifying documents in their core discovery productions which reference or describe some testing that has been performed. Plaintiffs have not yet had time to evaluate that proffer, and Plaintiffs maintain that it is still necessary for the Defendants to list all tests that have been performed and to provide sample results in order to assure that a relevant test is not missed.

Plaintiffs did confer with ZHP and experts regarding the documents identified by ZHP as setting forth some tests performed by ZHP. While still in need of a comprehensive list of tests and examples of the results, from each defendant, Plaintiffs have confirmed that the following test results set forth in the identified ZHP documents are needed:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

[redacted][8]

V. Conclusion

For the foregoing reasons, and those explained in Plaintiffs' opening letter brief (ECF 312), the Court should order Defendants to produce the documents requested by Plaintiffs, from the custodial and non-custodial sources identified by Plaintiffs, using the search terms proposed (and as narrowed) by Plaintiffs.

Respectfully,

ADAM M. SLATER

AMS

[8] Plaintiffs redacted these tests in the version of this brief filed on ECF because they are found in "confidential" documents. Plaintiffs have written to ZHP's counsel to confirm their agreement to produce these test results.

CERTIFICATE OF SERVICE

A true and correct copy of the foregoing was filed and served this 10th day of December 2019 on all counsel of record via the CM/ECF system of the United States District Court for the District of New Jersey.

/s/ Adam Slater
Adam Slater